Food and Drug Administration, HHS

- (iii) *Limitations*. Treated cattle must not be slaughtered for 4 days following the last treatment. A withdrawal period has not been established in preruminating calves. Do not use in calves to be processed for yeal.
- [61 FR 29479, June 11, 1996, as amended at 63 FR 53578, Oct. 6, 1998; 67 FR 45901, July 11, 2002; 69 FR 47362, Aug. 5, 2004. Redesignated and amended at 71 FR 39544, July 13, 2006; 73 FR 45612, Aug. 6, 2008; 76 FR 17338, Mar. 29, 2011; 78 FR 66264, Nov. 5, 2013]

§522.313c Ceftiofur sodium.

- (a) Specifications. Each milliliter of aqueous solution constituted from ceftiofur sodium powder contains 50 milligrams (mg) ceftiofur equivalents.
- (b) *Sponsors*. See Nos. 000409, 054771, and 068330 in §510.600(c) of this chapter.
- (c) Related tolerances. See §556.113 of this chapter.
- (d) Special considerations. Federal law restricts this drug to use by or on the order of a licensed veterinarian.
- (e) Conditions of use—(1) Swine—(i) Amount. 3 to 5 mg per kilogram (/kg) body weight by intramuscular injection for 3 consecutive days.
- (ii) Indications for use. For treatment and control of swine bacterial respiratory disease (swine bacterial pneumonia) associated with Actinobacillus pleuropneumoniae, Pasteurella multocida, Salmonella choleraesuis, and Streptococcus suis.
- (iii) *Limitations*. Treated pigs must not be slaughtered for 4 days following the last treatment.
- (2) Cattle—(i) Amount. 0.5 to 1.0 mg/lb body weight by intramuscular or subcutaneous injection for 3 days. Additional treatments may be given on days 4 and 5 for animals which do not show satisfactory response.
- (ii) Indications for use. For treatment of bovine respiratory disease (shipping fever, pneumonia) associated with Mannheimia haemolytica, Pasteurella multocida, and Histophilus somni. Also, for the treatment of acute bovine interdigital necrobacillosis (foot rot, pododermatitis) associated with Fusobacterium necrophorum and Bacteroides melaninogenicus.
- (iii) *Limitations*. Treated cattle must not be slaughtered for 4 days following the last treatment.

- (3) Sheep—(i) Amount. 0.5 to 1.0 mg/lb body weight by intramuscular injection for 3 days. Additional treatments may be given on days 4 and 5 for animals which do not show satisfactory response.
- (ii) Indications for use. For treatment of sheep respiratory disease (sheep pneumonia) associated with Mannheimia haemolytica and Pasteurella multocida.
- (4) Goats—(i) Amount. 0.5 to 1.0 mg/lb body weight by intramuscular injection for 3 days. Additional treatments may be given on days 4 and 5 for animals which do not show satisfactory response.
- (ii) Indications for use. For treatment of caprine respiratory disease (goat pneumonia) associated with Mannheimia haemolytica and Pasteurella multocida.
- (5) *Chickens*—(i) *Amount*. 0.08 to 0.20 mg as a single subcutaneous injection in the neck.
- (ii) Indications for use. For control of early mortality associated with Escherichia coli organisms susceptible to ceftiofur in day-old chicks.
- (6) Turkeys—(i) Amount. 0.17 to 0.5 mg as a single subcutaneous injection in the neck.
- (ii) *Indications for use*. For control of early mortality associated with *E. coli* organisms susceptible to ceftiofur in day-old poults.
- (7) Horses—(i) Amount. 2.2 to 4.4 mg/kg (1.0 to 2.0 mg/lb) body weight by intramuscular injection. Treatment should be repeated every 24 hours, continued for 48 hours after clinical signs have disappeared, and should not exceed 10 days. A maximum of 10 mL should be administered per injection site.
- (ii) Indications for use. For treatment of respiratory infections in horses associated with Streptococcus zooepidemicus.
- (iii) *Limitations*. Do not use in horses intended for human consumption.
- (8) Dogs—(i) Amount. 1.0 mg/lb (2.2 mg/kg) body weight by subcutaneous injection. Treatment should be repeated at 24-hour intervals for 5 to 14 days.

§ 522.380

(ii) *Indications for use*. For treatment of canine urinary tract infections associated with *E. coli* and *Proteus mirabilis*.

[53 FR 5369, Feb. 24, 1988, as amended at 55 FR 13768, Apr. 12, 1990; 56 FR 12119, Mar. 22, 1991; 57 FR 41862, Sept. 14, 1992; 59 FR 41666, Aug. 15, 1994; 59 FR 54518, Nov. 1, 1994; 60 FR 51719, Oct. 3, 1995; 61 FR 35130, July 5, 1996; 61 FR 66583, Dec. 18, 1996; 66 FR 21283, Apr. 30, 2001; 66 FR 32540, June 15, 2001; 69 FR 47362, Aug. 5, 2004. Redesignated and amended at 71 FR 39544, July 13, 2006; 74 FR 34236, July 15, 2009; 77 FR 29218, May 17, 2012; 79 FR 16185, Mar. 25, 2014]

§ 522.380 Chloral hydrate, pentobarbital, and magnesium sulfate.

- (a) Specifications. Each milliliter of solution contains 42.5 milligrams (mg) of chloral hydrate, 8.86 mg of pentobarbital, and 21.2 mg of magnesium sulfate.
- (b) Sponsor. See No. 054771 in $\S510.600$ (c) of this chapter.
- (c) Conditions of use—(1) Amount. For general anesthesia: Administer 20 to 50 milliliters per 100 pounds of body weight by intravenous injection until the desired effect is produced. Cattle usually require a lower dosage on the basis of body weight. As a sedative-relaxant: Administer at a level of one-fourth to one-half of the anesthetic dosage level.
- (2) *Indications for use.* For general anesthesia and as a sedative-relaxant in cattle and horses.
- (3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

 $[79~{\rm FR}~16185,\,{\rm Mar}.~25,\,2014]$

§522.390 Chloramphenicol.

- (a) Specifications. Each milliliter of solution contains 100 milligrams of chloramphenicol.
- (b) *Sponsor*. See Nos. 000859 and 054771 in §510.600(c) of this chapter.
- (c) Conditions of use. Dogs—(1) Amount. 5 to 15 milligrams per pound of body weight, intramuscularly or intravenously, every 6 hours. In severe infections, use 4 to 6 hour treatment intervals the first day. If no response is obtained in 3 to 5 days, discontinue use and reevaluate diagnosis.
- (2) Indications for use. Treatment of infections of the respiratory tract, the urinary tract, and enteritis and tonsil-

litis caused by organisms susceptible to chloramphenicol.

(3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian. Federal law prohibits the extralabel use of this drug in food-producing animals.

[57 FR 37331, Aug. 18, 1992, as amended at 65 FR 45877, July 26, 2000; 78 FR 17597, Mar. 22, 2013; 79 FR 16185, Mar. 25, 2014]

§522.460 Cloprostenol.

- (a) Specifications. Each milliliter of solution contains cloprostenol sodium equivalent to:
- (1) 125 micrograms (μg) of cloprostenol; or
 - (2) 250 µg of cloprostenol.
- (b) Sponsors. See sponsors in §510.600(c) of this chapter.
- (1) No. 000061 for use of product described in paragraph (a)(1) of this section as in paragraphs (c)(1)(i) and (c)(2) of this section.
- (2) Nos. 000061 and 068504 for use of product described in paragraph (a)(2) as in paragraphs (c)(1)(ii), (c)(1)(iii), and (c)(2) of this section.
- (c) Conditions of use in cattle—(1) Amount and indications for use—(i) Administer 375 μg by intramuscular injection to induce abortion in pregnant feedlot heifers from 1 week after mating until 4 1/2 months of gestation.
- (ii) Administer 500 μg by intramuscular injection for terminating unwanted pregnancies from mismatings from 1 week after mating until 5 months after conception; for treating unobserved (nondetected) estrus, mummified fetus, and luteal cysts; and for the treatment of pyometra.
- (iii) Administer 500 μg by intramuscular injection as a single injection regimen or double injection regimen with a second injection 11 days after the first, for scheduling estrus and ovulation to control the time at which cycling cows or heifers can be bred.
- (2) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16185, Mar. 25, 2014]